

## **REMARKS**

The Office Action dated July 17, 2006 has been carefully reviewed. Applicants request reconsideration of this application in light of the remarks presented herein.

### **§103 REJECTIONS – DEVANATHAN/McKELLOP**

In the previous Office Action dated March 21, 2006, claims 56-59, 61 and 124 were rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,645,594 to Devanathan et al. (hereinafter “Devanathan”) in view of U.S. Patent No. 6,165,220 to McKellop et al (hereinafter “McKellop”), whereas claims 49, 50, 52, and 55 were deemed allowable. Although Applicants believed that substantial legal arguments existed against the proposed Devanathan/McKellop combination, Applicants cancelled claims 56-59, 61, and 124, as well as withdrawn claims 62 and 63, in a good faith effort to advance prosecution of the subject application. Because only allowed claims remained after the cancellation of claims 56-59, 61-63, and 124, it was believed that the application had been placed in a condition for allowance. However, in the 7/17/06 Office Action, “upon further consideration” of the same references (i.e., Devanathan and McKellop), the Examiner has now rejected previously allowed claims 49, 50, 52, and 55.

Because the Examiner has now obviated Applicants’ effort to advance prosecution of this application, and because the arguments against the proposed Devanathan/McKellop combination apply in equal force to cancelled claims 56-59, 61, and 124, Applicants have herein reintroduced the subject matter of previously cancelled claims 56-59, 61, and 124 as new claims 125-132. In response to the two separate restriction requirements issued in this application, Applicants elected the invention drawn to the product of originally filed claims 49-61. Because newly added claims 125-132 reflect cancelled claims that were previously held to be drawn to the elected invention (i.e., canceled claims 56-59, 61, and 124), each of newly added claims 125-132 corresponds to the elected invention. In response to the

election of species issued in this application, Applicants elected to prosecute the claims of Species II (acetabular bearing, FIGS. 3-4). Each of newly added claims 125-129 and 132 is readable on the elected species. Applicants request that newly added claims 130-131 be withdrawn from consideration as being directed to a non-elected species, but request consideration of such claims when a generic claim is deemed allowable.

In light of the above, Applicants respectfully traverse the rejection of claims 49, 50, 52, and 55, along with the rejection of cancelled claims 56-59, 61, and 124 (now new claims 125-132), based on the combination of Devanathan and McKellop.

In the 7/17/06 Office Action, the Examiner indicated:

“...it would have been obvious to one of ordinary skill in the art at the time the invention was made to have irradiated the articulating surface of the Devanathan et al. bearing with e-beam irradiation, as taught by McKellop et al., *to produce gradient cross-linking on its articulating surface for wear resistance.*” (emphasis added).

It is a fundamental tenet of patent law that a prima facie case of obviousness cannot be established in the absence of some teaching, motivation, or suggestion supporting the modification or combination of the references relied upon in making the rejection. The rule of law for a finding of obviousness under 35 U.S.C. § 103(a) was reiterated recently by the Court of Appeals for the Federal Circuit as follows, “[w]hen patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness.” *In re Lee*, 277 F.3d 1338 at 1343, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002). The teaching or suggestion to make the claimed combination must be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. “To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly

suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

In an apparent attempt to establish a case of obviousness in the present case, the Examiner stated that it would have been obvious to e-beam irradiate the bearing of Devanathan “to produce gradient cross-linking on its articulating surface for wear resistance”. This is insufficient for a number of reasons. Firstly, for a teaching, motivation, or suggestion to be proper it must come from the prior art. In this regard, the Examiner has not identified where the prior art identifies the purported teaching, motivation, or suggestion that supports the need to increase the wear resistance of Devanathan’s bearing. The mere fact that McKellop teaches that wear resistance can be increased by e-beam irradiation is not, *ipso facto*, motivation to irradiate every bearing, let alone the specific composite bearing of Devanathan. Indeed, it is well known, and in fact acknowledged in McKellop at column 4, lines 30-41, that crosslinking polyethylene to increase its wear resistance necessitates the tradeoff of other physical properties. As such, it does not at all follow that one skilled in the art would always be motivated to crosslink a given bearing design to improve its wear characteristics since doing so could lead to an undesirable reduction in other physical properties.

In short, the Examiner has merely offered a conclusory, unsupported statement that effectively equates to a purported motivation to use the teachings of McKellop to crosslink every known prior art bearing. This simply cannot be the case. The mere statement of such a conclusory, unsupported notion on the record cannot function as a legally sufficient substitute for the required factual analysis clarified and confirmed in *Lee*. It is the Examiner’s burden to point to such motivation, and the Examiner has not done so.

*Furthermore, not only has the Examiner not offered a legally sufficient teaching, motivation, or suggestion to combine Devanathan and McKellop, it is believed that no such motivation exists since to do so would destroy the intent of the invention of*

***Devanathan.*** Indeed, Devanathan is directed to a method of fabricating orthopaedic bearings that leads to bearings that have “increased stiffness in the cup” and “reduced compression creep” relative to previous production techniques (see, e.g., column 2, lines 38-45). To do so, the inventive concept of Devanathan adds PMMA to the UHMWPE used to fabricate the bearing. In such a way, a bearing is produced that has increased stiffness and increased creep resistance. ***With this in mind, one skilled in the art would not be motivated to e-beam irradiate Devanathan’s bearing since doing so would actually REDUCE the stiffness of the bearing and LOWER its creep resistance.*** Indeed, it is well known that while crosslinking leads to increased wear resistance, it can also lead to the reduction of stiffness and creep resistance. McKellop acknowledges that crosslinking can lead to reduced stiffness. See, e.g., column 4, lines 30-33 where McKellop describes that crosslinking can lead to a reduction in the Young’s modulus of polyethylene (Young’s modulus is a measure of the stiffness of a given material). See also the Background of the present application where it is acknowledged that conventional (i.e., non-crosslinked) UHMWPE possess superior creep resistance relative to crosslinked UHMWPE. ***In short, to crosslink Devanathan’s bearing, as proposed by the Examiner, would lead to a reduction in its stiffness and creep resistance thereby destroying the intent of Devanathan’s invention of a bearing having increased stiffness and creep resistance.*** The CCPA and the CAFC have consistently held that when a §103 rejection is based upon a modification of a reference that destroys the intent, purpose, or function of the invention disclosed in the reference, such a proposed modification is not proper and a *prima facie* case of obviousness cannot be properly made.

Because the Examiner has not offered a legally sufficient teaching, motivation, or suggestion to combine Devanathan with McKellop, and in light of the overwhelming reasons against such a modification, it appears that the Examiner is using the Applicants’ application as a roadmap in developing his rejection. That is, the Examiner appears to be using hindsight reconstruction as a substitute for a factual basis for the rejection of the claims under 35 U.S.C.

§103. Such use of hindsight reconstruction is not proper. "There must be a reason apparent at the time the invention was made to a person of ordinary skill in the art for applying the teaching at hand, or the use of the teaching as evidence of obviousness will entail prohibited hindsight." *In re Nomiya, Kohisa, and Matsumura*, 509 F.2d 566, 184 USPQ 607 (CCPA 1975). "The Patent Office has the initial duty of supplying a factually basis for a rejection under 35 U.S.C. § 103. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis." *In re Rice*, 481 F.2d 1316, 178 USPQ 478, 479 (CCPA 1973).

As a result, the Examiner has not established a prima facie case of obviousness with regard to Applicants' claims 49, 50, 52, 55, 125-129 and 132. As such, the §103 rejection based on the Devanathan/McKellop combination should be withdrawn.

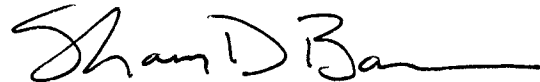
#### CONCLUSION

In view of the foregoing, it is submitted that this application is in a condition for allowance. Action to that end is hereby solicited.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages in other fees be charged, or any overpayment in fees be credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 265280-68002.

Respectfully submitted,

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